

Notice of Allowability

Application No.

09/744,016

Examiner

Sheridan L. Swope

Applicant(s)

VOELKEL, HELGE

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amtdt of June 14, 2004.
2. ☒ The allowed claim(s) is/are 1,5-20,22 and 24-27.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Applicant's response, on June 14, 2004, to the First Action on the Merits of this case mailed January 14, 2004, is acknowledged. It is acknowledged that applicants have cancelled Claims 2, 4, 21, amended Claims 1, 6, 7, 9-12, 14, 19, 20, and 22, and added New Claims 24-27. Claims 1, 3, 5-20, and 22-27 are pending. Claim 23 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected Inventions, there being no allowable generic or linking claim. Claims 1, 3, 5-20, 22, and 24-27 are hereby considered.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Cancel Claims 3 and 23.

For Claims 1 and 19, line 1, replace ~~–Method–~~ with ~~–A method–~~.

For Claims 3, 5-18, 20, 22, and 24-27, line 1, replace ~~–Method–~~ with ~~–The method–~~.

For Claim 1, line 9, replace ~~–the influence–~~ with ~~–an influence–~~.

For Claims 1, lines 3-4 and line 7, Claim 6, line 3, Claim 7, lines 2-3, Claim 9, lines 2-3, Claim 10, line 2-3 and line 4, Claim 12, line 2, Claim 19, line 4, line 7, and line 11, Claim 20, line 2-3, and Claim 22, line 2-3, replace ~~–Cu/Zn-superoxide–~~ with ~~–mammalian Cu/Zn-superoxide–~~.

For Claim 9, line 4, replace ~~–cell–~~ with ~~–cells–~~.

For Claim 15, replace ~~–which preferably carries a label–~~ with ~~–which carries a label–~~.

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For Claim 17, replace ~~–fluorescein–~~ with ~~–fluoresceine–~~.

For Claim 18, line 1, replace ~~–claim 3–~~ with ~~–claim 14–~~.

Authorization for this examiner's amendment was given in a telephone interview with Gary Nath's representative, Lee Heiman, on July 13, 2004.

Allowable Subject Matter

Claims 1, 5-20, 22, and 24-27 are allowed.

The following is an examiner's statement of reasons for allowance:

All elected Claims, 1, 5-20, 22, and 24-27, are limited to a method for screening for modulators of calcineurin enzymatic activity characterized in that a direct interaction between a mammalian calcineurin and a mammalian Cu/Zn superoxide dismutase (SOD) is monitored or a method wherein, after monitoring the direct interaction, the enzymatic activity of calcineurin is also assayed. The utility of said methods for screening for modulators of calcineurin activity is based on the following. Human Cu/Zn SOD protects human calcineurin from calcium-induced inactivation (pg 30, lines 23-34). As measured by laser fluctuation correlation spectroscopy, calcineurin and Cu/Zn SOD directly interact (pg 33, lines 24-32). A D⁹⁰A mutant of human Cu/Zn SOD that doesn't bind calcineurin, but only causes formation of calcineurin – Cu/Zn SOD aggregates, (pg 33, lines 32-34) provides only limited protection of calcineurin from calcium-induced inactivation (pg 31, lines 2-3). Thus, one of skill in the art would believe that, more likely than not, the ability of Cu/Zn SOD to protect calcineurin from calcium-induced inactivation is due to binding of Cu/Zn SOD to calcineurin. Therefore, a method for detecting modulators of calcineurin – Cu/Zn SOD interaction would have use as a means to identify agents able to either enhance or inhibit protection of calcineurin from inactivation by Cu/Zn SOD.

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Applicant's provided the following persuasive arguments in support of their request that the prior rejection of Claims 1, 5, 9, 13- 16, 18, and 19 under 35 U.S.C. 102(b), as being anticipated by Wang et al, and Claims 6-8 and 17 under 35 U.S.C. 103(a), as being unpatentable over Wang et al, 1996 in view of other teachings in the art, be withdrawn.

—That a careful reading of Wang, et al. clearly shows that the data disclosed by Wang et al. does not demonstrate the existence of a calcineurin/SOD complex. When conducting a gel filtration, molecules with higher molecular weight elute earlier from the column than molecules with lower molecular weight. According to figure 1, Wang, et al. conducted a gel filtration column on Sephadex 50, applying a supernatant of a brain homogenate. By measuring calcineurin activity before and after a preincubation in the presence CaCl_2 , they identified fractions containing Ca^{+2} -stable (CNs) and Ca^{+2} -inactivated (CNi) calcineurin. The fractions containing CNi eluted earlier than the fractions containing CNs. Wang interpreted these data to mean that the CNs fractions comprise a factor, later characterized as SOD, which forms a complex with calcineurin. If such a calcineurin/SOD complex (CNs) occurs, it would have a higher molecular weight than uncomplexed calcineurin (CNi) and would elute before, not after, CNi. Wang, et al. disclose only that calcineurin and SOD co-elute, in part, on gel filtration.— The Examiner agrees with this argument.

Thus, although Wang et al, 1996 show that Cu/Zn SOD protects calcineurin against inactivation (Fig 5), they do not show that calcineurin and Cu/Zn SOD bind to each other. Therefore, rejection of Claims 1-5, 9, 13- 16, 18, 19, and 21 under 35 U.S.C. 102(b), as being anticipated by Wang et al, and Claims 6-8 and 17 under 35 U.S.C. 103(a), as being unpatentable over Wang et al, 1996 in view of other teachings in the art, are withdrawn.

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Since calcineurin mediates the T-cell response, modulators of calcineurin activity, as discovered using the instant invention, are likely to be useful in regulating the immune response.

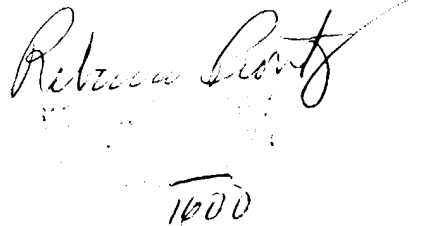
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.



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